

# Certificate of Registration



This is to certify that the Environmental Management System of:

## New England Biolabs, Inc.

240 County Road  
Ipswich MA 01938  
United States of America

(Central function listed above. See appendix for additional locations)

Applicable to:

**The design, development, production and distribution of molecular biology, reagents, and related products for applications in academic institutions, industry and OEM markets. Exclusions: the Day care facility, Gate house, Dunham Ridge, and Rowley-packaging facilities.**

Has been assessed and approved by  
National Quality Assurance, U.S.A., against the provisions of:

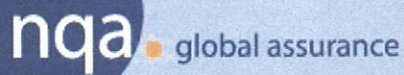
## ISO 14001:2015

Certificate Number: EN11948  
EAC Code: 34  
Certified Since: June 23, 2009  
Valid Until: May 21, 2027  
Reissued: May 22, 2024  
Cycle Issued: May 22, 2024

For and on behalf of NQA, USA.



# Certificate of Registration



Appendix to Certificate Number: EN11948

## Includes Facilities Located at:

**New England Biolabs, Inc.**  
Certificate Number EN11948  
240 County Road  
Ipswich MA 01938  
United States of America

The design, development, production and distribution of molecular biology, reagents, and related products for applications in academic institutions, industry and OEM markets. Exclusions: the Day care facility, Gate house, Dunham Ridge, and Rowley-packaging facilities.

**New England Biolabs, Inc.**  
Certificate Number EN11948  
428 Newburyport Turnpike  
Rowley MA 01969  
United States of America

The development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in academic and industrial research and OEM markets.

**New England Biolabs, Inc.**  
Certificate Number EN11948  
100 Cummings Center, Room 114Q  
Beverly MA 01915  
United States of America

The development and production of molecular biology and related reagents, in both standard and custom formats, for applications in academic and industrial research and OEM markets.

Certified Since: June 23, 2009

Valid Until: May 21, 2027

Reissued: May 22, 2024

Cycle Issued: May 22, 2024

# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Oxford Nanopore Technologies Plc  
Gosling Building  
Oxford Science Park  
Edmund Halley Road  
Oxford  
OX4 4DQ  
United Kingdom

Holds Certificate Number:

FS 686041

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

**The manufacture of nanopore sensor product, such as DNA/RNA sequencing, intended for use in regulated environments.**

For and on behalf of BSI:

\_\_\_\_\_  
Matt Page, Senior Vice President, EMEA Assurance

Original Registration Date: 2019-01-14

Effective Date: 2025-01-14

Latest Revision Date: 2024-12-03

Expiry Date: 2028-01-13

Page: 1 of 2



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No: FS 686041

Location	Registered Activities
Oxford Nanopore Technologies Plc Gosling Building Oxford Science Park Edmund Halley Road Oxford OX4 4DQ United Kingdom	The design, development, assembly and commercial sales of nanopore sensor products, such as DNA/RNA sequencing, intended for use in regulated environments.
Oxford Nanopore Technologies Plc Building R70, Room 5 Rutherford Appleton Laboratory Harwell Oxford Didcot OX11 0QX United Kingdom	Manufacture of nanopore sensor products, such as DNA/RNA sequencing, intended for use in regulated environments
Oxford Nanopore Technologies Plc MinION Building Becquerel Avenue Harwell Oxford Didcot OX11 0RA United Kingdom	The manufacture of nanopore sensor products, such as DNA/RNA sequencing, intended for use in regulated environments

Original Registration Date: 2019-01-14

Latest Revision Date: 2024-12-03

Effective Date: 2025-01-14

Expiry Date: 2028-01-13

Page: 2 of 2

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate CN17/20242



The management system of

# Nanjing Vazyme Biotech Co., Ltd.

Unified Social Credit Code: 91320192589435065R

Business Registration Address: No. 1-6 Floor, Eastern sector, Building C1-2, Red Maple Park, Kechuang Road, Economical and Technological Development Zone, Nanjing City

Business Operation Address: No. 5-8 Floor, Building D2, Red Maple Park, Kechuang Road, Economical and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

**ISO 9001:2015**

For the following activities

Develop and manufacture of the enzyme and premix (polymerase chain reaction, reverse transcription reaction, molecular cloning and mutagenesis, high throughput sequencing library preparation) used for research

This certificate is valid from 05 January 2024 until 18 January 2026 and remains valid subject to satisfactory surveillance audits.

Issue 7. Certified since 19 January 2017

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by  
Jonathan Hall  
Global Head - Certification Services

SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
t +44 (0)151 350-6666 - www.sgs.com

The certification information can be verified on the web site of Certification and Accreditation Administration of the People's Republic of China  
[www.cnca.gov.cn](http://www.cnca.gov.cn)



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# Nanjing Vazyme Biotech Co., Ltd.

ISO 9001:2015

Issue 7
<b>Sites</b>
<p>Nanjing Vazyme Biotech Co., Ltd.                  Unified Social Credit Code: 91320192589435065R                  Business Registration Address: No. 1-6 Floor, Eastern sector, Building C1-2, Red Maple Park, Kechuang Road, Economical and Technological Development Zone, Nanjing City                  Business Operation Address: No. 5-8 Floor, Building D2, Red Maple Park, Kechuang Road, Economical and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China                  Develop of the enzyme and premix (polymerase chain reaction, reverse transcription reaction, molecular cloning and mutagenesis, high throughput sequencing library preparation) used for research</p>
<p>Nanjing Vazyme Biotech Co., Ltd.                  Unified Social Credit Code: 91320192589435065R                  Business Registration Address: No. 1-6 Floor, Eastern sector, Building C1-2, Red Maple Park, Kechuang Road, Economical and Technological Development Zone, Nanjing City                  Business Operation Address: No. 5 Runhua Road, Nanjing Economic and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China                  Manufacture of the enzyme and premix (polymerase chain reaction, reverse transcription reaction, molecular cloning and mutagenesis, high throughput sequencing library preparation) used for research</p>
<p>Nanjing Vazyme Biotech Co., Ltd.                  Unified Social Credit Code: 91320192589435065R                  Business Registration Address: No. 1-6 Floor, Eastern sector, Building C1-2, Red Maple Park, Kechuang Road, Economical and Technological Development Zone, Nanjing City                  Business Operation Address: No. 1-4 Floor, No. 9, Daoqianghe Road, Nanjing Economic and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China                  Manufacture of the enzyme and premix (polymerase chain reaction, reverse transcription reaction, molecular cloning and mutagenesis, high throughput sequencing library preparation) used for research</p>
<p>Nanjing Vazyme Biotech Co., Ltd.                  Unified Social Credit Code: 91320192589435065R                  Business Registration Address: No. 1-6 Floor, Eastern sector, Building C1-2, Red Maple Park, Kechuang Road, Economical and Technological Development Zone, Nanjing City                  Business Operation Address: Room 207, No. 1 Shugang Road, Nanjing Economic and Technological Development Zone, Nanjing City Jiangsu Province, P.R. China                  Warehousing of the enzyme and premix (polymerase chain reaction, reverse transcription reaction, molecular cloning and mutagenesis, high throughput sequencing library preparation) used for research</p>



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# Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Oxford Nanopore Technologies Plc  
Gosling Building  
Oxford Science Park  
Edmund Halley Road  
Oxford  
OX4 4DQ  
United Kingdom

Holds Certificate Number:

FS 686041

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

**The design, development, manufacture and commercial sales of nanopore sensor products, such as DNA/RNA sequencing, intended for use in regulated environments**

For and on behalf of BSI:

\_\_\_\_\_  
Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2019-01-14

Latest Revision Date: 2022-01-05

Effective Date: 2022-01-14

Expiry Date: 2025-01-13

Page: 1 of 2



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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000  
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.

Certificate No: FS 686041

Location	Registered Activities
Oxford Nanopore Technologies Plc Gosling Building Oxford Science Park Edmund Halley Road Oxford OX4 4DQ United Kingdom	The design, development, manufacture and commercial sales of nanopore sensor products, such as DNA/RNA sequencing, intended for use in regulated environments
Oxford Nanopore Technologies Plc Building R70, Room 5 Rutherford Appleton Laboratory Harwell Oxford Didcot OX11 0QX United Kingdom	Manufacture of nanopore sensor products, such as DNA/RNA sequencing, intended for use in regulated environments
Oxford Nanopore Technologies Plc MinION Building Becquerel Avenue Harwell Oxford Didcot OX11 0RA United Kingdom	The design, development and manufacture of nanopore sensor products, such as DNA/RNA sequencing, intended for use in regulated environments

Original Registration Date: 2019-01-14

Latest Revision Date: 2022-01-05

Effective Date: 2022-01-14

Expiry Date: 2025-01-13

Page: 2 of 2

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BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.  
A Member of the BSI Group of Companies.



# Certificate

We hereby certify the company

**biotechrabbit GmbH**  
**Volmerstraße 9**  
**12489 Berlin**  
**Germany**

with the sites listed in the attachment the introduction and application of a

## **Quality management system according to EN ISO 9001**

in the scope

design and development, production, marketing and distribution of molecular biology products,  
proteins and reagents

An audit by mdc has proven that this quality management system meets the requirements of the following  
standard:

EN ISO 9001:2015 - ISO 9001:2015  
Quality management systems – Requirements

Valid from 2024-09-15  
Valid until 2027-09-14

Registration No. D1417500013  
Report No. P24-00727-300318

Stuttgart, 2024-09-02

  
Certification Body



Sites included in the certification:

Location	Scope
biotechrabbit GmbH Volmerstraße 9, 12489 Berlin Germany	marketing and distribution of molecular biology products, proteins and reagents
biotechrabbit GmbH Volmerstraße 9a, 12489 Berlin Germany	design and development, production including quality control, warehouse and logistics of molecular biology products, proteins and reagents

Stuttgart, 2024-09-02

  
Certification Body

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. SZ 2308167

TÜV Rheinland Nederland B.V. certifies the management system of:

Certificate Holder: **Magtivio B.V.**  
Daelderweg 9  
6361 HK NUTH  
Netherlands

Scope: Design, development, manufacture and distribution of magnetic separation solutions for the pre-treatment of body fluids in R & D.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: Issue date: 2024-07-20  
Expiry date: 2027-07-05  
First certification 2021



R.L. Kruit, LFM Systems  
TÜV Rheinland NL B.V.  
Westervoortsedijk 73, 6827 AV Arnhem  
P.O. Box 2220, 6802 CE Arnhem  
The Netherlands

# Certificate of Registration

**nqa** global assurance

This is to certify that the Quality Management System of:

## **New England Biolabs, Inc.**

240 County Road  
Ipswich MA 01938  
United States of America

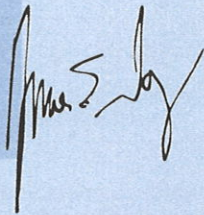
(Central function listed above. See appendix for additional locations)

applicable to:

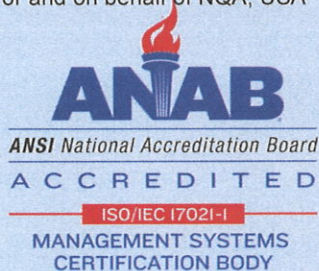
**The design, development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.**

has been assessed and approved by  
National Quality Assurance, U.S.A., against the provisions of:

### **ISO 9001:2015**



For and on behalf of NQA, USA



Certificate Number: 11948  
EAC Code: 34  
Certified Since: November 3, 2006  
Valid Until: March 4, 2027  
Reissued: October 25, 2024  
Cycle Issued: March 5, 2024

Appendix to Certificate Number: 11948

**Includes Facilities Located at:**

**New England Biolabs, Inc.**  
Certificate Number 11948  
240 County Road  
Ipswich MA 01938  
United States of America

The design, development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.

**New England Biolabs, Inc.**  
Certificate Number 11948  
428 Newburyport Turnpike  
Rowley MA 01969  
United States of America

The development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in academic and industrial research and OEM markets.

**New England Biolabs, Inc.**  
Certificate Number 11948  
100 Cummings Center, Room 114Q  
Beverly MA 01915  
United States of America

The development and production of molecular biology and related reagents, in both standard and custom formats, for applications in academic and industrial research and OEM markets.

**New England Biolabs, Inc.**  
Certificate Number 11948  
320 Newburyport Turnpike  
Rowley MA 01969  
United States of America

The packaging, warehousing and shipping of molecular biology and related reagents, for applications in academic and industrial research and OEM markets.

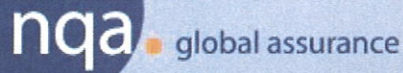
Certified Since: November 3, 2006

Valid Until: March 4, 2027

Reissued: October 25, 2024

Cycle Issued: March 5, 2024

# Certificate of Registration



Appendix to Certificate Number: 11948

## Includes Facilities Located at:

### **New England Biolabs (UK), Ltd**

Certificate Number 11948  
73-77 Knowl Piece  
Wilbury Way, Hitchin Herts SG4 OTY  
United Kingdom

Sales, marketing, distribution and technical support of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.

### **New England Biolabs (UK), Ltd**

Certificate Number 11948  
67 Knowl Piece  
Wilbury Way, Hitchin Herts SG4 OTY  
United Kingdom

Storage of packaging material

### **New England Biolabs GmbH**

Certificate Number 11948  
Bruningstr. 50; GEB. B852 D-65926  
Frankfurt am Main  
GERMANY

Sales, marketing, distribution and technical support of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.

### **New England Biolabs, Pte. Ltd**

Certificate Number 11948  
114 Lavender Street  
#07-58 CThub2  
Singapore 338729  
Republic of Singapore

Sales, marketing, distribution and technical support of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.

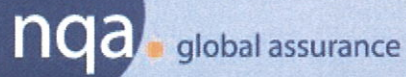
Certified Since: November 3, 2006

Valid Until: March 4, 2027

Reissued: October 25, 2024

Cycle Issued: March 5, 2024

# Certificate of Registration



Appendix to Certificate Number: 11948

## Includes Facilities Located at:

**NEB Lyophilization Sciences Ltd**  
Certificate Number 11948  
178 Brook Drive, Milton Park  
Abingdon, Oxfordshire OX14 4SD  
United Kingdom

The design, development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.

Certified Since: November 3, 2006

Valid Until: March 4, 2027

Reissued: October 25, 2024

Cycle Issued: March 5, 2024

Reg. Number	20983 - M	Valid from	2024-01-30
First issue date	2024-01-30	Last change date	2024-01-30
Valid until	2027-01-29		

## Quality Management System Certificate **UNI CEI EN ISO 13485:2021**

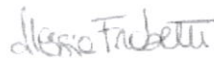
We certify that the Quality Management System of the Organization:

### **MAGTIVIO B.V.**

is in compliance with the Standard UNI CEI EN ISO 13485:2021 for the following products/services:

Design, development, manufacture and supply of IVD Medical Devices by magnetic solutions.

Medical Devices Division Manager  
Alessia Frabetti



The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 pag.



# Certificate

We hereby certify the company

**biotechrabbit GmbH**  
**Volmerstraße 9**  
**12489 Berlin**  
**Germany**

with the sites listed in the attachment the introduction and application of a

## Quality management system according to EN ISO 13485

in the scope

design and development, production, marketing and distribution of molecular biology products,  
proteins and reagents for in-vitro diagnostics

An audit by mdc has proven that this quality management system meets the requirements of the following  
standard:

EN ISO 13485:2016 + AC:2018 + A11:2021 - ISO 13485:2016  
Medical devices – Quality management systems – Requirements for regulatory purposes

Valid from 2024-09-15  
Valid until 2027-09-14

Registration No. D1417500014  
Report No. P24-00727-300314

Stuttgart, 2024-09-02



Certification Body



Sites included in the certification:

Location	Scope
biotechrabbit GmbH Volmerstraße 9, 12489 Berlin Germany	marketing and distribution of molecular biology products, proteins and reagents for in-vitro diagnostics
biotechrabbit GmbH Volmerstraße 9a, 12489 Berlin Germany	design and development, production including quality control, warehouse and logistics of molecular biology products, proteins and reagents for in-vitro diagnostics

Stuttgart, 2024-09-02



Certification Body



This is to certify that the Quality Management System of:

**New England Biolabs, Inc.**

240 County Road  
Ipswich MA 01938  
United States of America

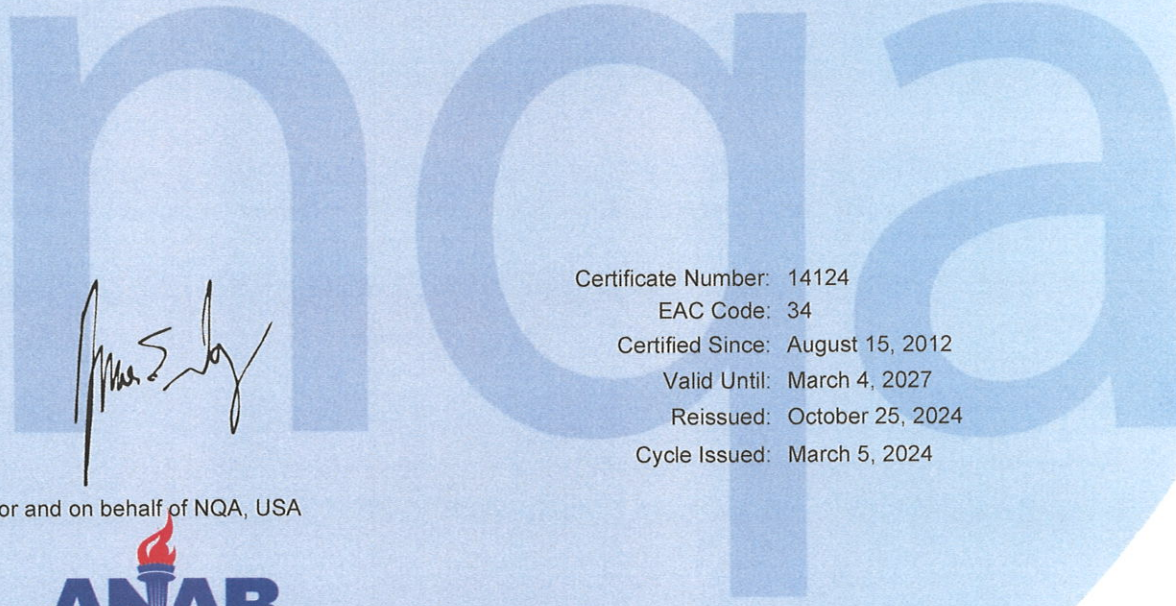
Central function listed above. See appendix for additional locations

applicable to:

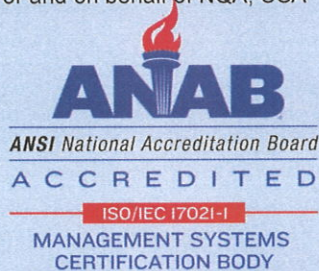
**The design, development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.**

has been assessed and approved by  
National Quality Assurance, U.S.A., against the provisions of:

**ISO 13485:2016**

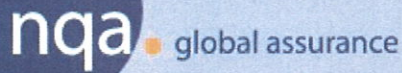


For and on behalf of NQA, USA



Certificate Number: 14124  
EAC Code: 34  
Certified Since: August 15, 2012  
Valid Until: March 4, 2027  
Reissued: October 25, 2024  
Cycle Issued: March 5, 2024

# Certificate of Registration



Appendix to Certificate Number: 14124

## Includes Facilities Located at:

**New England Biolabs, Inc.**  
Certificate Number 14124  
240 County Road  
Ipswich MA 01938  
United States of America

The design, development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.

**New England Biolabs, Inc.**  
Certificate Number 14124  
428 Newburyport Turnpike  
Rowley MA 01969  
United States of America

The development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in academic and industrial research and OEM markets.

**New England Biolabs, Inc.**  
Certificate Number 14124  
100 Cummings Center, Room 114Q  
Beverly MA 01915  
United States of America

The development and production of molecular biology and related reagents, in both standard and custom formats, for applications in academic and industrial research and OEM markets.

**New England Biolabs, Inc.**  
Certificate Number 14124  
320 Newburyport Turnpike  
Rowley MA 01969  
United States of America

The packaging, warehousing and shipping of molecular biology and related reagents, for applications in academic and industrial research and OEM markets.

Certified Since: August 15, 2012

Valid Until: March 4, 2027

Reissued: October 25, 2024

Cycle Issued: March 5, 2024

Appendix to Certificate Number: 14124

**Includes Facilities Located at:**

**New England Biolabs (UK), Ltd**

Certificate Number 14124  
73-77 Knowl Piece  
Wilbury Way, Hitchin Herts SG4 0TY  
United Kingdom

Sales, marketing, distribution and technical support of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.

**New England Biolabs (UK), Ltd**

Certificate Number 14124  
67 Knowl Piece  
Wilbury Way, Hitchin Herts SG4 0TY  
United Kingdom

Storage of packaging material

**New England Biolabs GmbH**

Certificate Number 14124  
Bruningstr. 50; GEB. B852 D-65926  
Frankfurt am Main  
GERMANY

Sales, marketing, distribution and technical support of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.

**New England Biolabs, Pte. Ltd**

Certificate Number 14124  
114 Lavender Street  
#07-58 CThub2  
Singapore 338729  
Republic of Singapore

Sales, marketing, distribution and technical support of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.

Certified Since: August 15, 2012

Valid Until: March 4, 2027

Reissued: October 25, 2024

Cycle Issued: March 5, 2024

# Certificate of Registration

**nqa** global assurance

Appendix to Certificate Number: 14124

**Includes Facilities Located at:**

**NEB Lyophilization Sciences Ltd**  
Certificate Number 14124  
178 Brook Drive, Milton Park  
Abingdon, Oxfordshire OX14 4SD  
United Kingdom

The design, development, production and distribution of molecular biology and related reagents, in both standard and custom formats, for applications in both academic and industrial research and OEM markets.

Certified Since: August 15, 2012

Valid Until: March 4, 2027

Reissued: October 25, 2024

Cycle Issued: March 5, 2024

Certificate CN22/42004

The management system of

# Nanjing Vazyme Biotech Co., Ltd.

Building D2, Red Maple Park, Kechuang Road, Economic and Technological Development Zone,  
Nanjing City, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms and injection parts used for in vitro diagnostic medical devices

This certificate is valid from 07 January 2025 until 06 January 2028 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 07 January 2022

Certified activities performed by additional sites are listed on subsequent pages.

*L. Moran*

Authorised by

Liz Moran  
Business Manager

SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
t +44 (0)151 350-6666 - www.sgs.com



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Certificate CN22/42004, continued  
**Nanjing Vazyme Biotech Co., Ltd.**



**ISO 13485:2016**

**EN ISO 13485:2016**

Issue 5

**Sites**

Nanjing Vazyme Biotech Co., Ltd.

Building D2, Red Maple Park, Kechuang Road, Economic and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China

Human resources, purchasing and sales management in support of Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms and injection parts used for in vitro diagnostic medical devices

Nanjing Vazyme Biotech Co., Ltd.

No. 5 Runhua Road, Nanjing Economic and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China

Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms

Nanjing Vazyme Biotech Co., Ltd.

No. 9 Daoqianghe Road, Nanjing Economic and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China

Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms

Nanjing Vazyme Material Technology Co., Ltd.

Room PA2-01, No. 1 Shugang Road, Nanjing Economic and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China

Manufacture of injection parts used for in vitro diagnostic medical devices

Nanjing Vazyme Biotech Co., Ltd.

Room 207, No. 1 Shugang Road, Nanjing Economic and Technological Development Zone, Nanjing City, Jiangsu Province, P.R. China

Warehousing support of Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms



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Certificate CN22/42004

The management system of

# Nanjing Vazyme Biotech Co., Ltd.

Building D2, Red Maple Park, Kechuang Road, Economic and Technological Development Zone,  
Nanjing City, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**

**EN ISO 13485:2016**

For the following activities

Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms and injection parts used for in vitro diagnostic medical devices

Digitally signed by Olaru Victoria

Date: 2025.03.15 10:22:45 EET

Reason: MoldSign Signature

Location: Moldova

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This certificate is valid from 07 January 2025 until 06 January 2028 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 07 January 2022

Certified activities performed by additional sites are listed on subsequent pages.

*L. Moran*

Authorised by

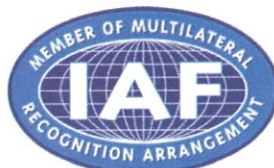
Liz Moran

Business Manager

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

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Certificate CN22/42004, continued  
**Nanjing Vazyme Biotech Co., Ltd.**



**ISO 13485:2016**

**EN ISO 13485:2016**

Issue 5

**Sites**

Nanjing Vazyme Biotech Co., Ltd.  
Building D2, Red Maple Park, Kechuang Road, Economic and Technological Development Zone, Nanjing City,  
Jiangsu Province, P.R. China

Human resources, purchasing and sales management in support of Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms and injection parts used for in vitro diagnostic medical devices

Nanjing Vazyme Biotech Co., Ltd.  
No. 5 Runhua Road, Nanjing Economic and Technological Development Zone, Nanjing City,  
Jiangsu Province, P.R. China

Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms

Nanjing Vazyme Biotech Co., Ltd.  
No. 9 Daoqianghe Road, Nanjing Economic and Technological Development Zone, Nanjing City,  
Jiangsu Province, P.R. China

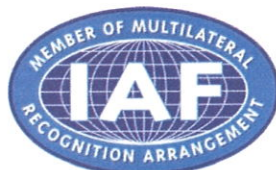
Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms

Nanjing Vazyme Material Technology Co., Ltd.  
Room PA2-01, No. 1 Shugang Road, Nanjing Economic and Technological Development Zone, Nanjing City,  
Jiangsu Province, P.R. China

Manufacture of injection parts used for in vitro diagnostic medical devices

Nanjing Vazyme Biotech Co., Ltd.  
Room 207, No. 1 Shugang Road, Nanjing Economic and Technological Development Zone, Nanjing City,  
Jiangsu Province, P.R. China

Warehousing support of Manufacture of molecular enzymes and premixes used for PCR (Polymerase Chain Reaction), QPCR (Quantitative Polymerase Chain Reaction), gene sequencing technology platforms



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# Certificate of Registration

INFORMATION SECURITY MANAGEMENT SYSTEM - ISO/IEC 27001:2013

This is to certify that:

Oxford Nanopore Technologies Plc  
Gosling Building  
Oxford Science Park  
Edmund Halley Road  
Oxford  
OX4 4DQ  
United Kingdom

Holds Certificate Number:

IS 667479

and operates an Information Security Management System which complies with the requirements of ISO/IEC 27001:2013 for the following scope:

**The Oxford Nanopore Technologies Plc Information Security Management System to incorporate all information assets used in the research, commercial and production activity of proprietary Nanopore based sensing technology and associated services. This is in accordance with Statement of Applicability version 4.0, dated 12/08/2022.**

For and on behalf of BSI:

\_\_\_\_\_  
Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2017-08-15

Latest Revision Date: 2023-07-18

Effective Date: 2023-08-15

Expiry Date: 2025-10-31

Page: 1 of 2



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Location	Registered Activities
Oxford Nanopore Technologies Plc Gosling Building Oxford Science Park Edmund Halley Road Oxford OX4 4DQ United Kingdom	The Oxford Nanopore Technologies Plc Information Security Management System to incorporate all information assets used in the research, commercial and production activity of proprietary Nanopore based sensing technology and associated services. This is in accordance with Statement of Applicability version 4.0, dated 12/08/2022.
Oxford Nanopore Technologies Plc MinION Building Becquerel Avenue Harwell Oxford Didcot OX11 0RA United Kingdom	The Oxford Nanopore Technologies Plc Information Security Management System to incorporate all information assets used in the research, commercial and production activity of proprietary Nanopore based sensing technology and associated services. This is in accordance with Statement of Applicability version 4.0, dated 12/08/2022.

Original Registration Date: 2017-08-15

Latest Revision Date: 2023-07-18

Effective Date: 2023-08-15

Expiry Date: 2025-10-31

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